

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 6882.90-6304	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2005/002202	International filing date (day/month/year) 25 January 2005 (25.01.2005)	Priority date (day/month/year) 26 January 2004 (26.01.2004)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant HOME DIAGNOSTICS, INC.			

<p>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p> <p>3. This report contains indications relating to the following items:</p> <table> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> <p>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).</p>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of issuance of this report 27 July 2006 (27.07.2006)	
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 28 JUN 2005

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To: see form PCT/ISA/220		Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)
Applicant's or agent's file reference see form PCT/ISA/220		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US2005/002202	International filing date (day/month/year) 25.01.2005	Priority date (day/month/year) 26.01.2004
International Patent Classification (IPC) or both national classification and IPC C12Q1/00		
Applicant HOME DIAGNOSTICS INC.		

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2005/002202

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - in written format
 - in computer readable form
 - c. time of filing/furnishing:
 - contained in the international application as filed.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2005/002202

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims No: Claims	1-33
Inventive step (IS)	Yes: Claims No: Claims	1-33
Industrial applicability (IA)	Yes: Claims No: Claims	1-33

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: WO 03/091717 A (HOME DIAGNOSTICS, INC) 6 November 2003 (2003-11-06)

D2: US 2002/084196 A1 (LIAMOS CHARLES T ET AL) 4 July 2002 (2002-07-04)

2. Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-33 is not new in the sense of Article 33(2) PCT.

The subject-matter of claim 1, relating to a test strip for measuring glucose in blood sample, is already disclosed in documents D1 and D2:

- D1 discloses systems and methods for blood glucose sensing, wherein the test strip for measuring the glucose in blood sample comprises a first insulating sheet, at least four electrodes, a plurality of electrical contacts, a plurality of conductive traces, an auto-on conductor, a first and a second dielectric layer, a reagent layer, a second insulating sheet and wherein, the slot defines a sample chamber in the test strip and the distal end of the slot vents the sample chamber, said slot being dimensioned to draw said blood sample in trough said proximal end of the slot by capillary action (see claim 1).

- D2 discloses a small volume sensor for determining the concentration of an analyte, such as glucose, in a biological fluid, such as blood, using techniques such as colorimetry, amperometry or potentiometry, and wherein the sensor contains at least four

electrodes (see pages 1-12).

The additional features of claims 2-10 are also known from D1 (see claims 2-9 and pages 7-11) and D2 (see pages 1-12 and claims 1-8) and therefore these claims are also not novel (Article 33(2) PCT).

Claims 11, relating to a test strip, and claims 21 and 26, relating to a method of making a plurality of test strips, are also not novel (Article 33(2) PCT); their subject-matter is already known from D1 (see claims 1-24 and figures 1-21) and D2 (see claims 1-8, 12-22).

The additional features of dependent claims 12-20, 22-25 and 27-33 are also disclosed in D1 (see pages 2-4, 7-43; claims 1-24; and figures 1-21) and D2 (see pages 1-12; claims 1-8, 12-22; and figures 1-21) and therefore these claims are also not considered to be novel (Article 33(2) PCT).

- 3.1 The use of general statements in the description which imply that the extent of protection may be expanded in some vague and not precisely defined way (see the term "spirit of the invention" on page 47) is not allowable (Article 6 PCT; see Guidelines III-4.3.a).
- 3.2 References to "co-pending U.S. patent application serial numbers" (see page 1) should be replaced by the corresponding publication numbers, provided the publication date was prior to the effective date of the present application. Moreover, the statement on page 1, lines 1-9 has no bearing on the invention or its background art, being irrelevant (Rule 9-1(iv) PCT).

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